

REMARKS/ARGUMENTS

Reconsideration of this application in light of the above amendments and following comments is courteously solicited.

Applicants respectfully request the examiner to reconsider his rejection of previously submitted independent claim 16 and independent claim 28 as well as the claims which depend therefrom in light of the following comments. The examiner rejected claims 16 and 28 under 35 U.S.C. 102(b) as being anticipated by Yoon '849. It is submitted that the examiner's rejection is in error and should be withdrawn.

The US Patent '849 discloses a safety penetrating instrument for use with forming an endoscopic portal for establishing communication with anatomical cavities wherein tissue and organ structures are protected from the tip of the penetrating member. The apparatus comprises a portal sleeve, a safety shield and a retractable penetrating member.

It is stated that the invention is in general characterised in a safety penetrating instrument for establishing a portal in a wall of an anatomical cavity. The instrument is said to be generally characterised in having a penetrating member with an extended position where a distal end of the penetrating member protrudes distally from a distal end of the portal sleeve. The penetrating member also has a retracted position proximally spaced from the extended position. A distally biased safety shield is disposed between the portal sleeve and the penetrating member and is movable relative to the portal sleeve between an extended safety shield rest position protecting the penetrating member distal end when the penetrating member is retracted and the safety shield retracted position exposing the penetrating member 36 distal end when a penetrating member is extended.

Retracting means is provided for moving the penetrating

member 36 from the penetrating member extended position to the penetrating member retracted position; means is also provided for manually moving the penetrating member 36 from the penetrating member retracted position to the penetrating member extended position. Locking means is provided for locking the penetrating member 36 in the penetrating member extended position while permitting a predetermined amount of proximal movement of the penetrating member during penetration of the anatomical cavity wall. As disclosed in the drawings the penetrating member 36 has an elongated shaft or body which is telescopically fitted over a guide tube 54 extending distally from a rear wall 48. In fact, whilst the penetrating member 36 has a hollow portion which is mounted on the guide tube 54, the tip of the penetrating member 36 is solid. Thus, the device disclosed in this patent has a penetrating member in the form of a trocar, i.e. a needle with a solid end which is incapable of having fluid flow therethrough.

The penetrating member 36 terminates proximally as a transverse flange 56 disposed between walls of a rail member 58. The penetrating member has a laterally extending flange disposed within the rail member 58 and a bias member 72 in the form of a coil spring disposed between the flange 56 and a rearward wall 68 of the rail member 58 to bias the penetrating member distally. In this way a retracting member 74, which is another coil spring, is mounted between the rail member and an inner wall 53 of a hub 44 to bias the penetrating member 36 in a proximal direction to a retracted position. The retracting member 74 is disposed around the penetrating member 36 and mounted in compression between the rail member 58 and the inner wall 53 to bias the rail member 58 and therefore the penetrating member 36 in a proximal direction to the retracted position.

where the distal end of the penetrating member 36 is disposed proximally of the distal end 76 of a safety shield 42.

There is also disclosed a locking end releasing mechanism 78 for locking the penetrating member 36 in an extended position. This is shown in Figure 1. This locking and releasing mechanism releases the rail member 58 by virtue of a complicated latching system.

Further, the penetrating member flange 56 extends towards a top wall 50 of the hub 44 and a post 104 extends from the penetrating member flange 56 through a longitudinal slot 106 formed in the top wall of the hub to terminate at a handle 108 disposed within an elongate trough-like recess 109. The handle 108 can be coupled with the penetrating member 36 directly or via the rail member 58. The handle 108 can be grasped and manually moved distally along the slot 106 formed in the top wall of the hub 44 to move the penetrating member 36 from the retracted position to the locked extended position.

The safety shield 42 extends from a distal end 76 to a proximal flange 110 disposed between the hub front wall 46 and the inner wall or partition 53 proximally spaced from the hub front wall. A bias member 114 in the form of a helical coil spring is disposed around the penetrating member 36 and held in compression between the safety shield flange 110 and the hub inner wall 53 to bias the safety shield 42 distally toward a rest position.

In use, the device of US Patent 5,584,849 is normally provided in the condition illustrated in Figure 3 with the safety shield 42 in the extended rest position and the penetrating member in the retracted position. Thus, the distal end 60 of the penetrating member is proximally spaced from the distal end of the safety shield 42 to protect the sharp tip 64

of the penetrating member 36 prior to use. In order to move the penetrating member 36 to the extended position shown in Figure 1 the handle 108 is grasped to move the penetrating member 36 and thus the rail member 58 distally until the rail member rearward wall 68 rides over latch 88 to be latched in the extended position with the rail member rearward wall 68 locked against a distal latching surface 92.

This position can be visually observed by a user by noting the position of the handle 108 at a distal end of the slot 106 when the penetrating member is presented for use. The penetrating member 36 can move proximally against the bias of bias member 72 in the extended position in response to forces acting on the penetrating member distal end such as the force from tissue contact during penetration of an anatomical cavity wall.

Similarly, the safety shield 42 can move proximally against the bias of the bias member 114 in response to forces acting on the safety shield distal end 76.

Thus, both the safety shield 42 and the penetrating member 36 are free to move proximally in response to tissue resistance during penetration. Therefore, the alignment of the safety shield distal end 76 with the penetrating member junction can be substantially maintained in order to ease penetration. When penetration of an anatomical cavity wall is commenced force from tissue contact on the safety shield and penetrating member distal end 76 and 60 will cause the safety shield and penetrating member to move together proximally against the bias of respective bias members 114 and 72. Once the penetrating member 36 enters the anatomical cavity the counter force on the safety shield 42 and the penetrating member 36 distal end caused by tissue contact is reduced. This allows bias members 114 and

72 to move the safety shield and the penetrating member distally. It follows that the penetrating member moves proximally to the retracted position wherein the penetrating member distal end 60 is proximally spaced from the safety shield distal end 76 to protect the sharp tip of the penetrating member. Then the penetrating unit 24 including the penetrating member 36 can be withdrawn from the portal unit 22 leaving the portal sleeve in place within the anatomical cavity to serve as a portal for introducing medical instruments therethrough.

Whilst there is a substantial detailed description of the structure and use of the device of Figures 1 to 3 of US Patent 5,584,849 there is no suggestion that once use has been completed that the device is rendered safe in a way which cannot be readily reversed. Thus, following completion of the action described above and withdrawal of the instrument there is no reason at all why the handle 108 cannot be moved forward again in the slot 106 so as to move the point 60 of the penetrating member 36 distally to a position where it is located distally of the safety shield 42 and is therefore exposed as shown in Figures 1 and 2. This can lead to needlestick injuries in personnel handling the device. As the penetrating member 36 has already been used this is extremely dangerous.

Further, as described above, the device is supplied with the penetrating member 36 in a retracted position. It is subsequently manually moved distally so as to put the penetrating member in an active position.

By way of comparison the needle apparatus of the present invention is primarily designed to practically eliminate the possibility of a needlestick injury occurring after the apparatus has been used. The present main claim recites that the apparatus comprises a tubular needle. This is entirely

different from the trocar disclosed in the citation. Also, the apparatus further comprises a hub in which the needle is fixedly mounted adjacent a proximal end of the needle such that the needle and the hub are arranged to move longitudinally together at all times.

Further, the needle and sleeve have a first position in which the needle extends from the sleeve and a second position in which the sharp point of the needle is located within the sleeve.

Still further, the arrangement is such that when the needle has been withdrawn to the second position after use and the sleeve is latched the sleeve is prevented from being retracted relative to the needle. This means that the used sharp point cannot be inadvertently or deliberately re-exposed.

By comparison, in the citation the penetrating member is a trocar which is incapable of transmitting fluid. Also, the penetrating member 36 is slideably mounted in the hub 44 as can be seen in the various positions illustrated in Figures 1 to 3 of the specification.

Further, after use the penetrating member 36 can be moved distally relative to the safety shield 42 so that the end 60 of the penetrating member is re-exposed. Thus, in effect, the safety shield 42 is retracted relative to the penetrating member.

In the present invention the fact that the sleeve is latched and is prevented from being retracted relative to the needle is absolutely critical for prevention of needlestick injuries. There is no means available in the apparatus of the present invention to retract the sleeve member once it has been latched after use.

In the specification of the present application at page 6

it is stated that the sleeve 28 can be used for fluid transfer from or to the living tissue in which it is inserted. It is also stated that the needle 12 remains in the fluid flow path at all times. Clearly the trocar disclosed in the citation cannot remain in a fluid flow path at all times because there is simply no fluid flow path for it to remain in.

The principle purpose of the apparatus of the present invention is to enable fluid to be transferred into an anatomical cavity or tissue or for fluid to be removed therefrom. Clearly this is not the case with the apparatus of the citation which is solely designed to place the endoscopic portal in the anatomical cavity or tissue.

As can be seen from the foregoing, the '849 patent is not at all relevant to the claimed subject matter of the instant application. The examiner in paragraph 10 of his office action states that the needle in the '849 document is mounted to the hub such that they move together longitudinally. As discussed above and as clearly shown from a review of Figures 1-3 of the '849 patent, the examiner is in error. Clearly it is seen from Figures 1-3 that the needle is not mounted to the hub such that they move together longitudinally. The examiner further states in paragraph 15 that the needle of the Yoon apparatus is inherently in the fluid flow path of the apparatus at all times. Again this is in error. As indicated in the comments above, the needle of the '849 patent is not in a fluid flow path at all because it is a trocar with a solid end so that there is no possibility of fluid flow through the apparatus. Accordingly it can not be in a fluid flow path.

In light of the foregoing comments it is submitted that the examiner's rejection is in error and should be withdrawn.

An earnest and thorough attempt has been made by the

undersigned to resolve the outstanding issues in this case and place same in condition for allowance. If the Examiner has any questions or feels that a telephone or personal interview would be helpful in resolving any outstanding issues which remain in this application after consideration of this amendment, the Examiner is courteously invited to telephone the undersigned and the same would be gratefully appreciated.

It is submitted that the claims as amended herein patentably define over the art relied on by the Examiner and early allowance of same is courteously solicited.

If any fees are required in connection with this case, it is respectfully requested that they be charged to Deposit Account No. 02-0184.

Respectfully submitted,
Maxwell Edmund Whisson et al.

By 

Gregory P. LaPointe
Attorney for Applicant
Reg. No. 28,395
Tel: (203) 777-6628
Fax: (203) 865-0297

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I, Rachel Piscitelli, hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:
"Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313" on October 19, 2006.

